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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,722	03/12/2002	Nobuo Ishiyama	2554-9	2663
23117	7590	09/20/2004	EXAMINER	
NIXON & VANDERHYE, PC 1100 N GLEBE ROAD 8TH FLOOR ARLINGTON, VA 22201-4714			KOSAR, ANDREW D	
			ART UNIT	PAPER NUMBER
			1654	

DATE MAILED: 09/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/913,722

Applicant(s)

ISHIYAMA ET AL.

Examiner

Andrew D Kosar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The Examiner notes that the formula of the claimed compound in claim 1 will be noted as (I). The structural formulae for the claimed compounds of claims 31-34 are (II), (III), (IV), and (V), respectively.

Group I, claim(s) 2-4, drawn to compounds of formula (I), wherein R^1 is variable.

Group II, claim(s) 5 and 6, drawn to compounds of formula (I), wherein Y is linear and is variable.

Group III, claim(s) 7-9, drawn to compounds of formula (I), wherein Y is cyclic and is variable.

Group IV, claim(s) 10 and 11, drawn to compounds of formula (I), wherein Y is generically -N-(carbocycle)- and is variable.

Group V, claim(s) 12, drawn to compounds of formula (I), wherein R^2 is variable.

Group VI, claim(s) 13 and 14, drawn to compounds of formula (I), wherein R^3 is variable.

Group VII, claim(s) 15-19, drawn to compounds of formula (I), wherein D is variable.

Group VIII, claim(s) 20, drawn to 115 distinct compounds of formula (I).

Group IX, claim(s) 21 and 22, drawn to compositions comprising compounds of formula (I).

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Group X, claim(s) 23 and 26, drawn to a method of increasing GH levels in a patient.

Group XI, claim(s) 24 and 25, drawn to a method treating or preventing diseases.

Group XII, claim(s) 27, drawn to a method for treating osteoporosis.

Group XIII, claim(s) 28, drawn to a method for treating bone fractures, wounds, or burns.

Group XIV, claim(s) 29, drawn to a method to increase the rate and extent of growth of animals, to increase the milk or wool production of animals, or for the treatment of ailments.

Group XV, claim(s) 30, drawn to a method for making compounds of formula (I).

Group XVI, claim(s) 31, drawn to a method of making compounds of formula (II).

Group XVII, claim(s) 32, drawn to a method of making compounds of formula (III).

Group XVIII, claim(s) 33, drawn to a method of making compounds of formula (IV).

Group XIX, claim(s) 34, drawn to a method of making compounds of formula (V).

Claim 1 link(s) inventions I-IX. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

If Applicant Elects Group VII, drawn to claims 15-19, Applicant is required to further select from the following groups.

Group VIIa, claim(s) 16, drawn to compounds of formula (I), wherein D is defined as in claim 15, and R⁸ is such that R²¹ is variable.

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Group VIIb, claim(s) 17, drawn to compounds of formula (I), wherein D is defined as in claim 15, and R⁸ does not comprise R²¹.

Group VIIc, claim(s) 18, drawn to compounds of formula (I), wherein D is defined as in claim 15, and R⁸ comprises R¹⁶⁻¹⁸.

Group VIId, claim(s) 19, drawn to compounds of formula (I), wherein D is defined as any one of the 60 distinct structures as drawn.

Claim 15 link(s) inventions VIIa-VIId. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions listed as Groups I-XIX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Because of the breadth of Claim 1, claim 1 is anticipated by Pollak, *et al*^a.

One embodiment of claim 1 is where R¹ is "substituted alkyl"; X is CO; Y is n=0, R⁴ is H, R⁵ is H, R⁶ is "substituted alkyl"; R² is H; R³ is "substituted alkyl"; and D is "substituted amino", formula (I) reads upon a tetrapeptide X-X-X*-X, with the proviso that X* is not glycine.

As such, any tetrapeptide would meet the limitations of claim 1. Pollak, *et al*. teaches the peptide dimethylglycine-serine-cysteine-glycine, wherein cysteine is protected before bonding to a gold surface (See footnote (19), Scheme 1, and

^aA Pollak, et al. J. Am. Chem. Soc. (1999) 121, 11593-11594.

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Supporting Information). This tetrapeptide fully anticipates instant claim 1, and therefore the instant claims lack unity of invention.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Claims 1-34 are drawn to numerous distinct possible products reading upon formula (I), such as a peptide or an alkyl amine compound with a single amide bond. A peptide and an alkyl amine are structurally distinct inventions.

In view of the selected Group, Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

If Applicant selects Group IX, Applicant is further required to elect a single species of growth hormone.

If Applicant selects Group X, Applicant is further required to elect a single species of growth hormone.

If Applicant selects Group XI, Applicant is further required to elect a single species of disease or condition.

If Applicant selects Group XIII, Applicant is further required to elect a single species of a growth factor and a single species of method.

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If Applicant selects Group XIV, Applicant is further required to elect a single species of the method.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does

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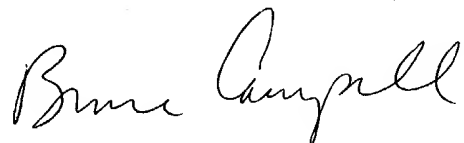
not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew D. Kosar whose telephone number is (571)272-0913. The examiner can normally be reached on Monday - Friday 8am-430pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571)272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Andrew D. Kosar, Ph.D.
Patent Examiner
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A handwritten signature in cursive script that reads "Bruce Campell".

BRUCE R. CAMPELL, PH.D
SUPERVISORY PATENT EXAMINER
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